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EXAMINER	
ELLIS, SUEZU Y	

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NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/507,094	MASPERO ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2004 and 21 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-63* is/are pending in the application.

4a) Of the above claim(s) *44-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the invention of Group I (claims 1-43) in the reply filed on November 21, 2007 is acknowledged. The traversal is on the ground(s) that the entire case can be searched without significant additional burden on the Examiner. This is not found persuasive because the search for each group requires different search queries. Furthermore, execution of a comprehensive search of all method and composition claims in the instant application would not only constitute an undue burden on the Examiner, but consideration of the findings of such a search for patentability determination would be unduly onerous. It is also noted that a comprehensive search for the presently claimed subject matter is not solely limited to a search of the classes and subclasses in which they are classified.

The requirement is still deemed proper and is therefore made FINAL.

Claims 44-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 21, 2007.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 7, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The abstract of the disclosure is objected to because in line 1 "a biocompatible and biodegradable implant..." should be "A biocompatible and biodegradable implant..." (capitalize the "A"). Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:

On page 2, in the paragraph that stars with "From the prior art", line 2 recites "US-A-5,626". The US patent number is missing the last 3 digits. The specification should recite "US-A-5,626,861" instead.

Appropriate correction is required.

Claim Objections

Claim 27-29, 32 and 35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

With respect to claim 27, claim language recites the micropores are in the range of about 0.1 m to about 0.6 m. This limitation fails to limit the subject matter of claim 25,

which recites the micropores have an average diameter of about 0-10 μm. For examination purposes, claim language will be treated as the micropores having an average diameter of about 0.1 μm to about 6 μm.

Claims not specifically addressed are considered to also fail to further limit the subject matter due to their dependency.

Claims 32 and 35 are objected to because of the following informalities:

With respect to claim 32, in lines 2-3, claim language recites "two or more kinds of granules" and "said different kinds of granules". Claim language should be changed to "said two or more kinds of granules" for proper antecedent basis.

With respect to claim 35, claim language recites the polymer coating has a thickness in a range of about 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of the implant, which is redundant with that in claim 14.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 14, claim language recites "a major portion of said granules being coated". It is unclear what applicant means by "a major portion". Does applicant mean a majority of the granules, or a major portion of the surface area of the granules? Please clarify.

With respect to claim 18, it is unclear what applicant means by the granules being of a regular shape. Please clarify.

Claim 26 recites the limitation "the hollow granules" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is unclear what hollow granules applicant is referring to since claims 23 and 24 recite porous granules. It is unclear if applicant means the granules are hollow instead of porous, or if the implant has both hollow granules **and** porous granules as suggested by the wording of the claim language. Examiner further notes the specification does not appear have support for a combination of both porous and hollow granules. Please clarify.

With respect to claim 28, it is unclear if applicant means the granules have both micropores **and** macropores. Please clarify. For examination purposes, claim language will be interpreted as the granules have both micropores and macropores.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-18, 20-25, 28-30, 32, 33 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer et al. (US 5,338,772) in view of Ricci et al. (US 2002/0016636).

With respect to claims 14 and 15, Bauer et al. discloses a biocompatible and biodegradable implant for filling a cavity in a living organism comprising polymer-coated biocompatible and biodegradable granules fused together through polymer linkage (polymer bridges) (col. 5, lines 19-25), and the granules have a particle size of 0.5-1.5 mm (within the range of 350-2000 μm) (col. 4, lines 25-26), and the granules being made of a bioceramic (calcium phosphate) (col. 4, lines 13-15), and a major portion of said granules being coated with a polylactide and/or polyglycolide layer (col. 4, line 66 - col. 5, line 1; col. 5, lines 19-25). Bauer et al. fails to expressly disclose the polymer coating having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of the implant. Ricci et al. discloses a bioresorbable implant comprising calcium sulfate particles coated with resorbable polymers, wherein the resorbable polymer is made of polylactides or polyglycolides [0025]. Ricci et al. further discloses the polymer coating having a thickness of about 2 μm to about 50 μm and being a range of 0.1% to 50% by weight in order to control the resportion rate of the implant composition [0022], [0026]. It would have been an obvious design modification to one of ordinary to modify the thickness and/or the content of the polymer coating of Bauer et al. in order to attain the desired resorption rate of the implant composition, as taught by Ricci et al. [0022], [0026]. Further, it has

been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 16, the modified Bauer et al. discloses the calcium phosphate is selected from the group consisting of hydroxyapatite, tricalcium phosphate and tetracalcium phosphate (col. 4, lines 13-15).

With respect to claim 17, the modified Bauer et al. discloses the granules have a particle size of 0.5-1.5 mm which overlaps the claimed range (col. 4, lines 25-26). While the modified Bauer et al. fails to expressly disclose the range being exactly the same as that claimed, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 18, a regular shape of the granules is considered inherent since the granules inherently have a shape to them.

With respect to claim 20, the modified Bauer et al. fails to expressly disclose the thickness of the polymer being in a range of 5 μm to about 20 μm. Ricci et al. discloses the polymer coating having a thickness of about 2 μm to about 50 μm which overlaps the claimed range [0022]. It would have been an obvious design modification to one of ordinary to modify the thickness of the modified Bauer et al. in order to attain the desired resorption rate of the implant composition, as taught by Ricci et al. [0022]. Further, it has been held that where the general conditions of a claim are disclosed in

the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 21 and 22, the modified Bauer et al. discloses an open-pore structure is formed by polymer bridges (col. 3, lines 25-26), however fails to expressly disclose the pore size of macropores being an average diameter in a range of about 100 µm to about 500 µm, or about 200 µm to about 300 µm. However, Bauer et al. does disclose the pore size is in the range of 0.01 – 1 mm, therefore overlaps the claimed range (col. 5, lines 26-28). It would have been an obvious design modification to one of ordinary skill in the art to modify the pore size depending on the application. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 23 and 24, the modified Bauer et al. discloses the granules having pores, therefore considered to be a porous granule (col. 4, lines 27-28).

With respect to claim 25, the modified Bauer et al. discloses the porous granules include both micropores and the micropore size is between 1 and 100 µm. While the modified Bauer et al. fails to expressly claim the pore size being within the exact range as claimed, it would have been an obvious design modification to one of ordinary skill in the art to modify the desired pore size depending on the application. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 28 and 29, the modified Bauer et al. discloses the porous granules include both micropores and macropores (col. 4, lines 33-36). While the modified Bauer et al. fails to expressly disclose the macropores having an average diameter in the range of about 10 μm to about 500 μm, or about 100 μm to about 300 μm. Bauer et al. does the pore size is in the range of 0.01 – 1 mm, therefore overlaps the claimed range (col. 5, lines 26-28). It would have been an obvious design modification to one of ordinary skill in the art to modify the desired pore size depending on the application. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 30, the modified Bauer et al. discloses the implant further comprises at least one biological active substance that is integrated into the polymer, thus is in the biocompatible and biodegradable coating (col. 7, lines 38-53).

With respect to claims 32 and 33, the modified Bauer et al. discloses the granules are porous granules and implant is shaped in the required manner to accommodate the granules (col. 3, lines 62-65). However, Bauer et al. fails to expressly disclose the implant is made of different kinds of granules having different biocompatible materials and/or having polymer coatings that are distance from each other and/or having different equivalent diameters. Ricci et al. discloses calcium sulfate particles being coated with different polymers, combinations of coated and mixed polymers, or having a coating of different thickness thus having different diameters [0024]. It would have been obvious to one of ordinary skill in the art to modify the granules of the

modified Bauer et al. for the predictable result of modifying the rates of resorption, as taught by Ricci et al. [0024].

With respect to claims 41-43, the modified Bauer et al. discloses the granules are fused together by subjecting them within a mold to a heat treatment for about 3-5 minutes (within the range of 10 seconds and 5 minutes) (col. 6, lines 22-26). The modified Bauer et al. fails to expressly disclose the temperature range being between 70°C and 220°C, or about 75°C to about 90°C. However, Bauer et al. does disclose the polymer should be fusible in a temperature range less than 180°C (col. 5, lines 12-14). It would have been obvious to one of ordinary skill in the art to modify the temperature range of the heat treatment in order to control the amount of coating that occurs (col. 6, lines 28-43). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer et al. in view of Ricci et al. and further in view of Niwa et al. (US 4,429,691).

With respect to claim 19, the modified Bauer et al. addresses all the limitations of claims 14 and 18, and further discloses the material implant material can be used for filling bone cavities (col. 7, lines 27-28). The modified Bauer et al. fails to expressly disclose the shape of the granules being spherical. Niwa et al. discloses a filler for filling bone cavities having spherical shaped calcium phosphate granules (col. 6, lines 12-13). It would have been an obvious design choice to modify the shape of the

granules to be spherical in order to facilitate the filling of bone cavities, as taught by Niwa et al.

Claims 14-25 28-30 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nuwayser (US 5,648,097) in view of Bauer et al. and further in view of Ricci et al.

With respect to claims 14 and 15, Nuwayser discloses a biocompatible and biodegradable implant for filling a cavity in a living organism comprising polymer-coated biocompatible and biodegradable granules (particles) (col. 2, lines 26-39;), the granules being made of a bioceramic (calcium phosphate) (col. 4, lines 35-37), and a major portion of said granules being coated with a polylactide and polyglycolide polymer coating (Example X). Nuwayser also discloses the polymer coating being 15% by weight (Example X). Nuwayser discloses the granules having a particle size being in the range of one micron to several millimeters in diameter (col. 2, lines 12-15), however fails to expressly disclose the particle size within the exact range of 350-2000 μm. However, it is well known in the art of bone implants to utilize calcium phosphate particles having a particle size of 0.5-1.5 mm, as taught by Bauer et al. (col. 4 lines 25-26). It would have been obvious design choice to one of ordinary skill in the art to modify the particle size of the granules depending on the application, as taught by Ricci et al [0022]. Nuwayser also fails to expressly disclose the thickness of the polymer coating being in a range about 2 μm to about 300 μm. Ricci et al. discloses a bioresorbable implant comprising calcium sulfate particles coated with resorbable

polymers of polylactides or polyglycolides [0025]. Ricci et al. further discloses the polymer coating having a thickness of about 2 μm to about 50 μm and being a range of 0.1% to 50% by weight in order to control the resportion rate of the implant composition [0022], [0026]. It would have been an obvious design modification to one of ordinary to modify the thickness of the polymer coating for the predictable result of attaining a biodegradable implant with a desired resorption rate of the implant composition, as taught by Ricci et al. [0022], [0026]. Nuwayser further fails to expressly disclose the implant is made by fusing together the polymer-coated granules via polymer linkage. However this technique is known in the art of creating bone implants and fillers, as taught by Bauer et al. (col. 5, lines 19-25). It would have been obvious to one of ordinary skill in the art to fuse the polymer-coated granules together via polymer linkage for the predictable result of creating bone fillers or implants.

With respect to claim 16, the modified Nuwayser discloses the calcium phosphate is selected from the group consisting of hydroxyapatite and α- and β-tricalcium phosphates (col. 5, lines 17-28).

With respect to claim 17, Nuwayser fails to expressly disclose the particle size within the exact range of 500-1000 μm. However, Nuwayser does disclose the granules having a particle size being in the range of one micron to several millimeters in diameter (col. 2, lines 12-15), therefore it would have been obvious design choice to one of ordinary skill in the art to modify the particle size of the granules depending on the application, as taught by Ricci et al [0022].

With respect to claims 18 and 19, the modified Nuwayser discloses the granules are spherical shaped (col. 2, lines 12-13).

With respect to claims 20 and 37, the modified Nuwayser fails to expressly disclose the thickness of the polymer coating being in the range of about 5 μm to about 20 μm. Ricci et al. discloses the thickness of the polymer coating controls the resorption rate of the implant composition in a recipient site [0022]. It would have been an obvious design choice to one of ordinary skill to modify the thickness of the polymer coating in order to attain the desired resorption rate.

With respect to claims 21 and 22, the modified Nuwayser discloses the granules have a desired porosity (col. 4, lines 26-30), however fails to expressly disclose the granules having a pore size of the macropores being an average diameter in a range of about 100 μm to about 500 μm, or about 200 μm to about 300 μm. Bauer et al. discloses bone implants comprising granules impregnated with bioactive agent, where the granules have a pore size is in the range of 0.01 – 1 mm, therefore overlaps the claimed range (col. 5, lines 26-28). It would have been an obvious design modification to one of ordinary skill in the art to modify the pore size in order to create desired porosity for long term drug delivery, as taught by Nuwayser (col. 4, lines 26-30).

With respect to claims 23-25, 28 and 29, the modified Nuwayser discloses the granules have a desired porosity (col. 4, lines 26-30), however fails to expressly disclose the granules having both macropores and micropores, wherein the pore size of the micropores have an average diameter in the range of more than about 0 μm to about 10 μm, or about 0.1 μm to about 6 μm, and the particle size of the macropores

have an average diameter in a range of about 10 μm to about 500 μm, or about 100 μm to about 300 μm. Bauer et al. discloses bone implants comprising granules impregnated with bioactive agent having a combination of micropores and macropores (col. 4, lines 33-35) wherein pore sizes are in the range of 0.01 – 1 mm, therefore overlaps the claimed range (col. 5, lines 26-28). It would have been an obvious design modification to one of ordinary skill in the art to modify the pore size in order to create desired porosity for long term drug delivery, as taught by Nuwayser (col. 4, lines 26-30).

With respect to claim 30, the modified Nuwayser discloses at least one biological active substance (biologically active agent) being integrated into the granules (col. 4, lines 12-18).

With respect to claims 32 and 33, the modified Nuwayser discloses the biodegradable and biocompatible implant is made of two or more kinds of granules wherein the granules are made of different biocompatible materials (col. 5, lines 52-56), and the granules are porous (col. 4, lines 26-40).

With respect to claim 34, the modified Nuwayser discloses the granules are microparticles that are spherical shaped (microsphere) made of a biodegradable and biocompatible material (poly-DL-lactide-co-glycolide) and are loaded with at least one biologically active substance (col. 3, lines 52-54; col. 4, lines 12-25; Example X). Since more than one granule (microsphere) are used to create an implant, the granules are considered to be mixed with the claimed microspheres (microspherical granules are mixed together).

With respect to claims 35 and 36, the modified Nuwayser discloses the granules are spray-coated in a fluidized bed machine (Example X).

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nuwayser in view of Bauer et al. and further in view of Ricci et al. and further in view of Glajch et al. (US 6,455,024).

With respect to claims 26 and 27, the modified Nuwayser addresses all the limitations of claims 14 and 23-25, and further discloses the granules having a therapeutic drug. However the modified Nuwayser fails to expressly disclose the granules being hollow granules with at least one opening in the granule wall, wherein the opening in the granule wall is larger than the range of about 0.1 μm to 6 μm. Glajch et al. discloses implanting radiotherapeutic agents comprising polymer-coated porous particles having a single pore (hollow particles) ranging in particle size from about 0.2 to 500 μm, the pore size may correspondingly vary from about 0.2 to 500 μm (col. 4, line 20; col. 7, lines 36-54; col. 8, lines 28-39). It would have been an obvious design choice to one of ordinary skill in the art to modify the granules to be hollow granules with an opening in the wall as another means for delivering the therapeutic agent (col. 6, line 46 – col. 7, line 2). With respect to the size of the pore, it would have been an obvious design choice to one of ordinary skill in the art to modify the pore size in order to obtain desirable therapeutic effects (col. 6, lines 34-37).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nuwayser in view of Bauer et al. and further in view of Ricci et al. and further in view of Eitenmuller et al. (US 4,610,692).

With respect to claim 31, the modified Nuwayser addresses all the limitations of claim 31, however fails to expressly disclose the implant comprises mixtures of non-coated and polymer-coated granules that are fused together. Eitenmuller et al. an implant for filling bone cavities made of polylactide-coated granules and uncoated granules that are impregnated with a therapeutically-active ingredient (col. 11, lines 18-27; col. 12, lines 7-11). It would have been obvious to one of ordinary skill in the art to fuse together polymer-coated and non-coated granules in order to create an implant having a rapid-release and sustained-release of biologically active ingredient, as taught by Eitenmuller et al. (col. 7, lines 9-14).

Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nuwayser in view of Bauer et al. and further in view of Ricci et al. and further in view of Ruffieux et al. (WO 00/50104).

With respect to claims 38-40, the modified Nuwayser addresses all the limitations of claim 14, however fails to expressly disclose the granules being fused together in a mold in a pressurized CO_2 atmosphere under a pressure in a range of about 20-200 bar for at least about 3 seconds. Ruffieux et al. discloses a method of creating an implant utilizing polymer-coated particles containing calcium and phosphate-based minerals, wherein the polymer-coated particles are partially dissolved under pressure in a

gaseous solvent under sub-critical conditions, binding the particles together, expanding and removing the solvent and shaping the obtained porous combination of particles into the required form (implant), wherein the gaseous solvent is carbon dioxide (equivalent-abstract). Ruffiex et al. further discloses the pressure is about 62 bar and the granules are under pressure for 45 seconds (equivalent-abstract). It would have been obvious to one of ordinary skill in the art to utilize the fusing method of Ruffieux et al. for the predictable result of creating an implant with the desired porosity.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 14 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36, 42 and 43 of copending

Application No. 10/540323. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 36 and 42 of Application No. 10/540323 recite:

Biocompatible implant for the treatment of defects in a living organism such as bone defects or tooth extraction wounds, comprising at least one zone of impermeability to soft tissue and/or epithelial cells in-growth, wherein said implant is comprised of an open porous scaffold and a membrane covering at least a part of said scaffold and being sealed to it such that said scaffold and said membrane form a single piece of matter;

wherein said scaffold is comprised of **fused, biocompatible, biodegradable granules** selected from the group consisting of solid granules, porous granules, hollow granules, hollow granules with at least one opening in the granule, or a mixture thereof; said granules having an equivalent-diameter in a range between about 100 μm to about 2000 μm**, a major portion of said granules being coated with at least one biocompatible and biodegradable layer of a polymer selected from the group consisting of poly(α-hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarates), poly(amino acids), polysaccharides, polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or copolymers, terpolymers**

thereof, or blends of those polymers, said polymer coating having a thickness in a range between 1 μm to 300 μm; and

wherein **said granules having an equivalent-diameter in a range between about 500 μm to about 1000 μm** (*within the range of 350 to 2000 μm*).

The claims of Application No. 10/540323 fail to expressly recite the limitations of the granules being made of biopolymers, bioglasses, bioceramics or a mixture thereof, however it would have been an obvious design choice to one of ordinary skill in the art to modify the type of material for the predictable result of attaining the desired biocompatible property for the implant. Further it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

The claims of Application No. 10/540323 also fails to expressly the weight fraction of the polymer being about 4% to about 15% of the weight of the implant. However, the claim language, as worded, appears to be another way of expressing the thickness, and therefore is considered to be structurally equivalent to the thickness being between 2 μm and 300 μm. Examiner also notes that while the claims of Application No. 10/540323 recite the polymer coating having a thickness in a range between 1 μm to 300 μm instead of 2 μm to 300 μm, the thickness ranges are so similar that they are considered to be structurally equivalent. However, examiner also notes that where the general conditions of a claim are discloses in the prior art, discovering

the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Sharon E. Kennedy/
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